

Message Text

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ORIGIN HEW-06

INFO OCT-01 AF-10 EUR-12 EA-12 NEA-11 ISO-00 OES-07
SIG-03 /062 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VO
APPROVED BY OES/ENP/EN: WJWALSH, III
DHEW/PHS/OASH/OIH: REVANS
EA/ANP:TWAJDA(INFO)
NEA/IAI:MANDERSON(INFO)
EUR/NE:SWORREL(INFO)
EUR/NE:WNEWLIN(INFO)
EUR/WE:JDOBBINS(INFO)
EUR/CE:JHURLEY,JR(INFO)
AF/S:JTAYLOR(INFO)
EA/ANP:WGALLAGHER (INFO)

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P 262045Z JUN 78
FM SECSTATE WASHDC
TO AMEMBASSY CANBERRA PRIORITY
AMEMBASSY TEL AVIV PRIORITY
AMEMBASSY LONDON PRIORITY
AMEMBASSY THE HAGUE PRIORITY
AMEMBASSY BRUSSELS PRIORITY
AMEMBASSY PARIS PRIORITY
AMEMBASSY BERN PRIORITY
AMEMBASSY WELLINGTON PRIORITY
AMEMBASSY PRETORIA PRIORITY
AMEMBASSY KUALA LUMPUR PRIORITY

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KUALA LUMPUR PASS BRUNEI PRIORITY

E.O. 11652:N/A

TAGS: OGEN, EIND, ETRD, TBIO, AS, IS BX, UK, ;L, BE, FR, SZ,
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NZ, SF

SUBJECT:FDA ADVISORY - DEFECTIVE DIALYSIS UNIT (RECALL
T-108-8)

1. FDA ADVISES OF THE FOLLOWING MEDICAL DEVICE RECALL:
PRODUCT INVOLVED - PRODUCT IS PHYSIO-CONTROL CORP. PERITO-

NEAL DIALYSIS SYSTEM. SYSTEM CONSISTS OF TWO UNITS, THE DIALYSIS UNIT AND THE REVERSE OSMOSIS UNIT. THE DEFECT RELATES ONLY TO THE DIALYSIS UNIT.

2. PRODUCT IDENTIFICATION - BRAND NAME INVOLVED IS PHYSIO-CONTROL. THERE ARE NO PRIVATE LABELS. THE MODEL NUMBERS INVOLVED ARE PDS200, AND PDS300. SERIAL NUMBERS OF THE PDS200 UNITS ARE 1-45 (200 VOLT SYSTEMS) AND 1-170 (115 VOLT SYSTEMS).

3. MANUFACTURER/RECALLING FIRM - PHYSIO-CONTROL CORP., REDMOND, WA

4. REASON FOR ADVISORY - THE DIALYSIS UNITS WERE FOUND TO HAVE AN INHERENT ELECTRONIC CIRCUIT PROBLEM THAT COULD PRODUCE A FALSE CONDUCTIVITY READING AND AT THE SAME TIME PREVENT THE HIGH CONDUCTIVITY ALARM SYSTEM FROM OCCURRING

AT THE PROPER POINT. THIS DEFECT WAS FOUND TO OCCUR ONLY WHEN THE DIALYSATE TEMPERATURE AND CONDUCTIVITY OPERATED TOWARD THE UPPER LIMITS. THE TEMPERATURE MEASUREMENT CIRCUIT IS NOT AFFECTED.

5. THE MANUFACTURER HAD RECEIVED A COMPLAINT FROM TORONTO WESTERN HOSPITAL, TORONTO, CANADA, THAT A PATIENT HAD BECOME COMATOSE WHILE UNDERGOING PERITONEAL UNCLASSIFIED

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DIALYSIS AND SUBSEQUENTLY DIED. AUTOPSY ATTRIBUTED DEATH TO CHRONIC RENAL INSUFFICIENCY AND METABOLIC ENCEPHALOPATHY. AUTOPSY ALSO DISCLOSED HYPERNATRAEMIA (NA 160) AND HYPERGLYCAEMIA (SUGAR 525). THERE WAS NO EVIDENCE THAT THE DEATH WAS DUE TO A DIALYSIS SYSTEM MALFUNCTION.

6. THE HOSPITAL HAD REPORTED SOME PROBLEMS WITH THE CONDUCTIVITY READING HIGH AND DIFFICULTY IN LOWERING IT. (HE MACHINE HAD BEEN RECALIBRATED AFTER THE PATIENT'S DEATH, BEFORE THE MANUFACTURER COULD EVALUATE IT. THERE WAS NO RECORD OF THE TEMPERATURE OR CONDUCTIVITY LEVELS WHICH HAD BEEN USED.

7. BASED ON THE COMPLAINT AND ONGOING PRODUCT DEVELOPMENT TESTING OF THE CONDUCTIVITY AND TEMPERATURE MEASUREMENT CIRCUIT, THE FIRM FOUND THAT WHEN THE DIALYSATE TEMPERATURE REACHED 37.5 DEGREES CENTIGRADE THE CONDUCTIVITY READING BECAME NON-LINEAR AT A LEVEL OF PLUS 5 OR ABOVE. THE FIRM ADVISED FDA ON 1/24/78 AND MAILED A WARNING LETTER WITH THAT DATE.

8. FIRM SENT WARNING LETTER TO ALL DIRECT CONSIGNEES

AND A TWX TO FOREIGN CONSIGNEES. A MODIFICATION KIT
WILL BE SENT AS SOON AS COMPONENTS CAN BE ASSEMBLED AND
INSTRUCTIONS PRINTED.

9. POSTS ARE REQUESTED TO CONTACT CONSIGNEES TO VERIFY
IF THEY HAVE RECIEVED TWX FROM FIRM RE: WARNING. ANY
QUESTIONS CONSIGNEES MAY HAVE REGARDING ADVISORY SHOULD
BE REFERRED TO MANUFACTURER.

9. FOREIGN CONSIGNEES AS PROVIDED BY FIRM ARE:

PRINCE HENRY'S HOSPITAL, ST. KILDA ROAD, MELBOURNE 3004
AUSTRALIA - 9 UNITS

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BEILINSON MEDICAL CENTER, KUPAT CHOLIM HEALTH SERVICES
P.O.BOX 33016, TEL AVIV, ISRAEL - 1 UNIT

DIRECTOR OF MEDICAL SERVICES, BRUNEI, BORNEO - 1 UNIT

CARDIFF ROYAL INFORMARY, NEWPORT ROAD, CARDIFF, SOUTH
WALES, UNITED KINGODM - 1 UNIT

MR. JACQUES VAN DER LOOY, JAN THYSSENHOF 8, P.O.BOX 321
SOEST, THE NETHERLANDS

MR. ALLAN BRACK, HILEKES B.V. STARGARDIAAN 13, POSTUBUS
202, BUSSUM, THE NETHERLANDS

HILEKES MEDICAL SUPPLIES N/V SA, DE VILLEGASSTRAAT 122,
1820 STROMBEEK BEVER, BELGIUM

MR. SOL BENZAQUEN, BERNAS MEDICAL 7/9 REU DES COTTAGES,
75018 PARIS, FRANCE

ARMIN BOLLINGER, MED. ELEKTRONIK AND TECHNIK, FORCHSTR 4,
8610 USTER, SWITZERLAND

MR. MICHAEL A HARRISON, P.O. BOX 29020, FENDALTON,
CHRISTCHURCH, NEW ZEALAND

MR. J.H. BOORNE, H.I. CEMENTS PTY. LTD., 109 WICKS ROAD
P.O.BOX 110, NORTH RYDE, NSW 2113, AUSTRALIA

RDT ELEC-RONICS ENGINEERING LTD., P.O.BOX 21082 TEL AVIV,
46 SOKOLOV ST., RAMAT HASHARON, ISRAEL

RESEARCH SURGICAL (PTY) LTD., 32/36 DE VILLE STREET
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P.O.BOX 60118, LANGLAAGTE, JOHANNESBURG, SOUTH AFRICA VANCE

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Message Attributes

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Disposition Approved on Date:
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Subject: FDA ADVISORY - DEFECTIVE DIALYSIS UNIT (RECALL T-108-8)
TAGS: OGEN, EIND, ETRD, TBIO, AS, IS, BX, UK, NL, BE, FR, SZ
To: CANBERRA TEL AVIV MULTIPLE
Type: TE
vdkgvwkey: odbc://SAS/SAS.dbo.SAS_Docs/03ffed7f-c288-dd11-92da-001cc4696bcc
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